THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte MURRAY A. KAPLAN, JOSEPH B. BOGARDUS and
ROBERT K. PERRONE

_____

Appeal No. 1995-3047
Application No. 07/805,729[1]

_____

ON BRIEF

_____

Before WINTERS, WILLIAM F. SMITH and LORIN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

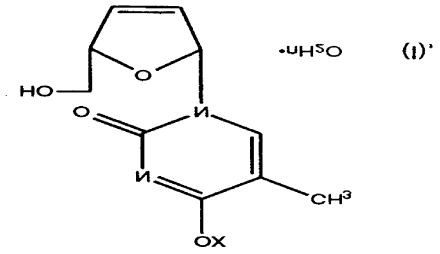
DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 24, which are all of the claims in the application.

Claims 1, 8 and 15 are representative:

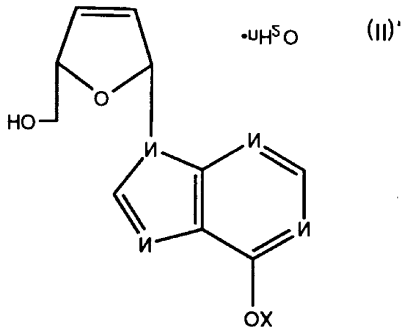
[1]Application for patent filed December 6, 1991. According to appellants, this application is a continuation-in-part of application no. 07/772,641, filed October 8, 1991, now abandoned, which is a continuation of application no. 07/652,454, filed February 7, 1991, now abandoned which is a continuation of application no. 07/514,261, filed May 1, 1990, now abandoned which is a continuation-in-part of application no. 07/352,065, filed May 15, 1989, now abandoned.

1. A highly water soluble, stable, crystalline salt of 2',3'-dideoxy-2',3'-didehydrothymidine of Formula (I):



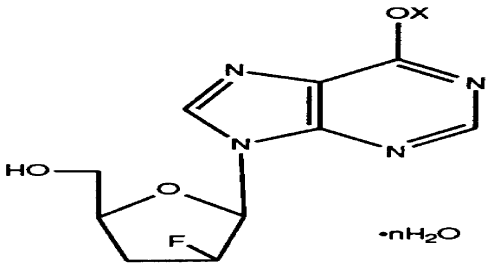
wherein X is an alkali or alkaline earth metal ion, an ammonium ion or a quaternary amino ion and n is 0.5 to 2.0.

8. A highly water soluble, stable, crystalline sodium salt of 2',3'-dideoxyinosine of Formula (II):



wherein X is an alkali or alkaline earth metal ion, an ammonium ion or a quaternary amino ion, and n is 0.5 to 2.0.

15. A highly water-soluble, stable, crystalline salt of 2',3'-dideoxy-2'-fluoroinosine of



(III).

Formula (III):

wherein X is an alkali or alkaline earth metal ion, an ammonium ion or a quaternary amino ion, and n is 0.5 to 2.0.

The references relied on by the examiner are:

Verheyden et al. (Verheyden)	3,817,982	Jun. 18, 1974
Mitsuya et al. (Mitsuya)	WO 87/01284	Mar. 12, 1987
Marquez et al. (Marquez) (European Patent Application)	0 287 313	Oct. 19, 1988
Lin et al. (European Patent Application)	0 273 277	Jul. 06, 1988

Lin et al., "Potent and Selective in Vitro Activity of 3'-Deoxythymidin-2'-ene (3'-Deoxy-2',3'-didehydrothymidine) Against Human Immunodeficiency Virus," Biochemical Pharmacology, vol. 36 no. 17, pgs. 2713-2718 (1987). (Lin)

Hamamoto et al. "Inhibitory Effect of 2',3-Didehydro-2',3'-Dideoxynucleosides on Infectivity, Cytopathic Effects, and Replication of Human Immunodeficiency Virus," Antimicrobial Agents and Chemotherapy, vol. 31, no. 6, pgs. 907-910 (1987). (Hamamoto)

Baba et al.(I), "Ribavirin Antagonizes Inhibitory Effects of Pyrimidine Dideoxynucleosides but Enhances Inhibitory Effects of Purine 2',3'-Dideoxynucleosides on Replication of Human Immunodeficiency Virus In Vitro,"Antimicrobial Agents and Chemotherapy vol. 31, no. 10, 1613-1617 (1987). (Baba(I))

Baba et al. (II), "Both 2',3'-Dideoxythymidine and its 2',3-Unsaturated Derivative (2',3'-Dideoxythymidinene) Are Potent and Selective Inhibitors of Human Immunodeficiency Virus Replication In Vitro," Biochemical Biophysical Research Communications., vol. 142, no. 1, pgs. 128-134 (1987). (Baba(II)

Balzarini et al., "Estimation of the Lipophilicity of Anti-HIV Nucleoside Analogues by Determination of the Partition Coefficient and Retention Time on a Lichrospher 60 RP-8 HPLC Column," Biochemical and Biophysical Research Communications., vol. 158, no. 2, pgs. 413-422 (January 1989). (Balzarini)

DeClercq, "Potential Drugs for the Treatment of AIDS," J. Antimicrobial Chemotherapy, Suppl. A, 23, pgs. 35-46 (1989).

In the answer, page 4, the examiner states that U.S Patent No. 4,861,759, issued August 29, 1989 to Mitsuya et al., is "equivalent" to International Publication No. WO 87/01284. Likewise, the examiner states that U.S. Patent No. 4,978,655, issued December 18, 1990 to Lin et al., is "equivalent" to the above-cited Lin et al.

publication appearing in Biochemical Pharmacology, vol. 36, pages 2713 through 2718 (1987). It is unclear just what the examiner means by the term "equivalent". Suffice it to say, however, that neither U.S Patent No. 4,861,759 or U.S. Patent No. 4,978,655 is set forth in the statement of rejections under 35 U.S.C. § 103 and, accordingly, we have not considered either of those patents in our deliberations.

The issues presented for review are: (1) whether the examiner erred in rejecting claims 1 through 24 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure; (2) whether the examiner erred in rejecting claims 22 through 24 under 35 U.S.C. § 112, first and second paragraphs, "as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same and/or for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention." (answer, page 6); (3) whether the examiner erred in rejecting claims 1 through 7 and 22 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Lin, Verheyden, Hamamoto, Baba (I), Baba (II), Balzarini, DeClercq, and EP 273,277; (4) whether the examiner erred in rejecting claims 8 through 14 and 23 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Balzarini, Verheyden, DeClercq, and International Publication No. WO 87/01284; and (5) whether the examiner erred in rejecting claims 15 through 21 and 24

under 35 U.S.C. § 103 as unpatentable over Marquez.

On consideration of the record, we shall not sustain these rejections.

DISCUSSION

In rejecting claims 1 through 24 under 35 U.S.C. § 112, first paragraph, the examiner argues that appellants' disclosure is enabling "only for claims limited in accordance with the specific embodiments"; that the terms "virus" and "viral infection" in claims 6, 13, 20, and 21 through 23 are too broad, i.e., not supported by an enabling disclosure; and that the term "mammal" in claims 6, 13 and 20 is too broad and not supported by an enabling disclosure. However, in the statement of rejection (Examiner's Answer, page 6), the examiner does not provide adequate reasons or evidence to support his position. We invite attention to the following statement in In re Armbruster, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975) quoting from In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 369-370 (CCPA 1971):

> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. . . .
>
> . . . it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement

> in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

The statement of rejection in the Examiner's Answer, page 6, amounts to a mere conclusion, unsupported by facts, that claims 1 through 24 are based on a non-enabling disclosure. The examiner has not complied with the appropriate legal standard for rejecting claims based on the enablement requirement of 35 U.S.C. § 112, first paragraph, and has not established a prima facie case of a non-enablement.

The rejection of claims 1 through 24 under 35 U.S.C. § 112, first paragraph, is reversed.

The examiner also argues that method claims 22 through 24 are incomplete for failing to recite a "host in need thereof". It follows, according to the examiner, that these claims do not comply with 35 U.S.C. § 112, first or second paragraphs. See the Examiner's Answer, page 6, lines 13 through 25. Again, the flaw with this rejection is a failure to set forth reasons or evidence supporting the examiner's position. The mere conclusion that claims 22 through 24 do not comply with 35 U.S.C. § 112, first and second paragraphs, is not enough. Simply stated, the examiner has not set forth adequate reasons or evidence which would establish a prima facie case of indefiniteness or lack of enablement for these claims.

The rejection of claims 22 through 24 under 35 U.S.C. § 112, first and second paragraphs, is reversed.

Each § 103 rejection presents the same question, namely, whether the particular salt forms of d4T, ddI and F-ddI recited in the appealed claims would have been obvious in view of the parent compounds d4T, ddI and F-ddI. We answer that question in the negative.

As can be seen from a review of appellants' claims, each salt contains 0.5 to 2.0 moles of water and variable X (appellants' terminology) is an alkali or alkaline earth metal ion, an ammonium ion, or a quaternary amino ion. According to the examiner, the cited prior art discloses parent compounds d4T, ddI and F-ddI, but does not disclose salt forms of those parent compounds. Nor does the examiner rely on "secondary" art to make up this difference. Rather, the examiner relies on Ex parte Matheson, 92 USPQ 255 (P. O. Bd. of Appeals 1951) for its discussion of "the question of patentability of salts of known compounds". See the Examiner's Answer, page 9, lines 5 through 13; page 10, lines 16 through 24; and page 11, lines 17 through 25.

The examiner's reliance on Ex parte Matheson is misplaced. In Matheson, the examiner rejected claims drawn to the copper, zinc and iron salts of tetra-isobutyl phenol sulfonic acid "as not patentably distinguishing" over the sodium salt of that same acid disclosed in the prior art. The Board of Appeals reversed the examiner's decision, holding

that disclosure of the sodium salt does not constitute sufficient evidence to support a rejection of the "remotely related" copper, zinc, and iron salts of the same acids. Cf In re Jones 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). (disclosure of the substituted ammonium salts of "dicamba", a genus which encompasses the claimed salt, does not constitute sufficient evidence to establish a prima facie case of obviousness). Here, we find that the disclosure of parent compounds is insufficient to support a conclusion of obviousness of claims reciting particular salt forms of those compounds, and our decision is entirely consistent with the decision reached in Matheson.

The rejection of all the appealed claims under 35 U.S.C. § 103 is reversed.

In conclusion, we do not sustain the examiner's prior art or non-prior art rejections. The examiner's decision rejecting claims 1 through 24 is reversed.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)	
WILLIAM F. SMITH	)	BOARD OF PATENT APPEALS AND

Administrative Patent Judge	)	INTERFERENCES
	)	
	)	
	)	
HUBERT C. LORIN	)	
Administrative Patent Judge	)	

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